**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

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| **IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION**<br><br>**THIS DOCUMENT RELATES TO:**<br><br>***Trinie Garcia-Valdez v. Ethicon, Inc. et al.***<br><br>**Case No. 2:14-cv-13951** | **Master File No. 2:12-MD-02327**<br>**MDL No. 2327**<br><br>**JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

**PLAINTIFF'S MEMORANDUM IN OPPOSITION OF DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT**

Plaintiff states as follows in opposition to Defendants' Motion for Partial Summary Judgment:

## INTRODUCTION AND STANDARD OF LAW

In Defendants' Motion, they ignore evidence directly contrary to its arguments, and also ask the Court to extend California law beyond its authority. To succeed on its Motion, Ethicon, must show that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). On a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).[1]

## STATEMENT OF MATERIAL FACTS[2]

[1] Plaintiff agrees that the substantive law of California applies to Plaintiff's claims.
[2] Plaintiff disputes Defendants' version of Undisputed Facts to the extent they differ from Plaintiff's Statement of Material Facts.

Ms. Garcia-Valdez was implanted with a Prolene Soft on June 29, 2007 by Dr. Raz to treat her stress urinary incontinence. (Ex. A, Medical Records of Trinie Garcia-Valdez at 1-5). Beginning in about 2012, Plaintiff began to experience painful intercourse, vaginal pain and discomfort, to which she never previously experienced, as well as recurrent stress urinary incontinence. (Ex. B, Garcia-Valdez Dep. at 12:6-19). Her pain during intercourse was excruciating and greatly affected her relationship with her husband. (Ex. A at 11-12; Ex. B at 110:5-9, 16). Plaintiff consulted with a doctor in July 2013 to discuss her issues. (Ex. A at 6-7). In January 2014, Plaintiff underwent a cystoscopy, where it was noted she had mesh erosion, dyspareunia, and prolapse. (Ex. A at 8-10). It was recommended she have a surgery to correct these issues. *Id.*.

On November 13, 2014, Plaintiff had the mesh removed by Dr. Raz due to vaginal pain, dyspareunia, and mesh erosion. (Ex. A at 13-14). After the removal of the mesh, her pain during intercourse and vaginal pain resolved. (Ex. B at 38:20-25, 40:10-16). Plaintiff continued to have stress urinary incontinence until a secondary procedure performed by Dr. Raz on July 9, 2015, where an autologous fascia lata was used. (Ex. A at 15-16; Ex. B at 40:3-9).

Prior to her 2007 procedure she recalls talking with Dr. Raz about the risks and receiving a pamphlet on risks and discharge instructions. (Ex. A at 17-20; Ex. B at 95:22-25). However, Plaintiff did not recall receiving any warning or instruction on painful intercourse or long-term pelvic pain. (Ex. B at 91:18-24). Though Plaintiff did have an additional surgery in 2015, the surgery did not include mesh, and her understanding was that Dr. Raz no longer used it in his practice. (Ex. B at 15:15-24).

**ARGUMENT**

## I. SUMMARY JUDGMENT IS NOT APPROPRIATE FOR PLAINTIFF'S FAILURE TO WARN CLAIM AND CAUSATION[3]

Defendants argue that Plaintiff's claim fails under failure to warn and causation because Plaintiff did not meet burden of showing the defective warning was a 'substantial factor' in producing her injuries. (Def. Mt. at 3-4). However, there is an abundance of evidence showing a genuine issue of material fact, and therefore Defendants' motion for summary judgement on this issue should be denied.

In California, when the learned intermediary doctrine applies, the plaintiff must show "…[1] that no warning was provided or the warning was inadequate, [and]…[2] that the inadequacy or absence of the warning caused the plaintiff's injury." *Motus v. Pfizer Inc.*, 196 F. Supp.2d 984, 991 (C.D. Cal. 2001) (*Motus I*) *aff'd sub nom. Motus v. Pfizer Inc.*, 358 F.3d 659 (9th Cir. 2004) (*Motus II*). Courts in California have held that this duty to warn about the known or knowable hazards of a drug or medical device is ongoing. *See Singleton v. Eli Lilly Co.*, No. 1:10-cv-02019-AWI-SKO, 2012 WL 2018536 at *3 (E.D. Ca. June 5, 2012) ("The duty to warn is a continuing duty, requiring a manufacturer to notify the medical profession of any side effects of a prescription drug which are subsequently discovered, and is based on the application of scientific knowledge at the time of manufacture and distribution of the drug").

In order for a manufacturer of a drug or device to be absolved of liability, the warning it provides to the physician must be adequate. *See Conte v. Wyeth*, 168 Cal. App. 4th 89, 98, n.5 (Cal. App. 1, 2008).; *see also Stewart v. Union Carbide Corp.*, 190 Cal. App. 4th 23, 29-30 (Cal. App. 2, 2010) (the warning provided to a sophisticated user was inadequate and, therefore, could not absolve the defendant manufacturer of liability where neither the sophisticated user nor the

[3] Defendants' motion does not argue against Plaintiff's first cause of action of negligence, only in strict liability. (Def. Mt. at 3-4).

manufacturer warned the plaintiff of the product at issue.) ("If Union Carbide and the sophisticated intermediary failed to give warnings, that should not absolve Union Carbide of responsibility.").

The adequacy of a warning is generally a question of fact. *Carlin v. Superior Court*, 56 Cal. Rptr. 2d 162, 168-69 (Cal. 1996). A warning is inadequate if it fails to "sufficiently alert the *user* to the possibility of danger." *Aguayo v. Crompton & Knowles Corp*., 228 Cal. Rptr. 768, 775 (Cal. Ct. App. 1986) (emphasis added). In a medical device case, the physician who implants the device is the "user." *Valentine v. Baxter Healthcare Corp*., 81 Cal. Rptr. 2d 252, 263 (Cal. Ct. App. 1999).

In this case, the IFU of the Prolene Soft mesh was insufficient for a physician such as Dr. Raz to understand the frequency and severity of the adverse events involved.[4] Plaintiff's general expert Dr. Donald R. Ostergard, M.D prepared a report presenting that that IFUs were inadequate insofar as they lack substantive risk information presented by physicians such as Dr. Raz. Particularly, the IFU does not warn of delayed visceral erosion and delayed intractable and untreatable pain. (Ex. D, Expert Report of Dr. Donald R. Ostergard, M.D. at 21). Plaintiff suffered injuries such as vaginal pain, dyspareunia, pelvic and erosion of the mesh (Ex. A at 6-7; Ex. B at 12:6-19), all of which were not warned about. (Ex. A at 17-20; Ex. B at 91:18-24).

The IFUs were inadequate because they were completely void of these important risks, which is information that physicians would need to know to factor into an associated risk/benefit analysis. One specific example is the lack of information to doctors about the degradation of the Prolene mesh, and its ability to cause flaking and fissuring and cause moderate to severe vaginal

[4] The Defendants' IFU for the Prolene Soft at time of implantation indicated the adverse events to include: "infection potentiation, inflammation, adhesion formation, fistua formation, and extrusion." (attached hereto as Exhibit C)

retraction. (Ex. D at 19-20). The IFU also did not warn of persistent inflammatory reaction by the weakened and degraded mesh in the body. *Id*. These risks make the Prolene mesh "unreasonably dangerous, defective and [unsuitable] to serve as the permanent implants that they have been represented by Ethicon to be." (Ex. E, Jimmy W. Mays General Expert Report at 5).

Because Defendants failed to provide adequate information about the effects of the materials, the additional adverse events, and the frequency and severity of the adverse events, thereby insufficiently warning of the possibility of the device's dangers, the adequacy of the warnings is a question of fact, and the court should deny Defendants' motion for summary judgement.

## II. FRAUD CLAIMS

Contrary to Defendants' assertions, Plaintiffs' negligence-based claims cannot be dismissed based on the court's disposition of Plaintiff's failure to warn claims. (Def. Mt. at 4-6). Defendants attempt to assert the same arguments this Court has already disposed of in *Sanchez v. Boston Scientific, Corp.* As this Court has previously ruled, "medical device manufacturers may be liable for design defects under the ordinary principles of negligence" in California. 2014 U.S. Dist. LEXIS, at *17. Thus, the Court can swiftly reject Defendants' argument on this point. In California, negligence theories survive summary judgment even when courts dismiss failure to warn claims for lacking causation under the learned intermediary doctrine. *Tucker v. Wright Med. Tech., Inc.*, No. 11-cv-03086, 2013 WL 1149717, at *10, 16 (N.D. Cal. March 19, 2013) (granting defendants' motion for summary judgment on plaintiff's strict liability and negligent failure to warn claim, but denying defendant's motion for summary judgment on plaintiff's negligence claim under California law); *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1487 n. 15, 81 Cal. Reptr. 2d 252 (Cal. Ct. App. 1999) (explaining that a negligent design

claim can stand alone without failure to warn claim in California because the two causes of action involve separate rights and duties). *Tucker* illustrations that California's learned intermediary doctrine does not bar every cause of action against a manufacturer or medical devices. 2013 WL 1149717. Applying *Motus I* and *Motus II*, that court granted summary judgment on the plaintiff's strict liability and negligent failure to warn claims because there was no evidence the defective warnings caused the plaintiff's injuries. *Id.* at 16. However, the learned intermediary doctrine did not bar the plaintiff's negligent design claim and that court denied summary judgment on that claim. *Id.* at *10. *Tucker* teaches that a plaintiff's negligence-based claims survive summary judgment even when the learned intermediary doctrine bars his or her strict liability or negligent failure to warn claims.

Under *Tucker* and *Valentine*, the following negligence-based claims survive summary judgment:

1. **Negligence**: *Friedman v. Merck & Co.*, 107 Cal. App. 4th, 454, 463, 131 Cal. Rptr. 2d 885, 890 (2003);

2. **Negligent Design**: *Chavez v. Glock, Inc.*, 207 Cal. App. 4th 1283, 1305, 144 Cal. Rptr.3d 326 (Cal. Ct. App. 2012);

3. **Negligent Misrepresentation**: *Apollo Capital Fund, LLC v. Roth Capital Partners, LLC*, 158 Cal. App. 4th 226, 70 Cal. Rptr. 3d 199 (Cal. Ct. App. 2007).

Summary judgment would therefore be inappropriate on Plaintiff's negligence-based claims because California's learned intermediary does not bar those claims.

Plaintiff has also offered evidence that Defendants breached their duty and did not act as a reasonable medical device manufacturer, including failing to warn physicians and patients of known risks. Plaintiff also offered evidence that Defendants engaged in extreme and outrageous

conduct including but not limited to failing to inform physicians and patients of risks and complications that Ethicon knew to be associated with the Prolene Soft mesh devices. For all of these reasons, Defendants' motion for summary judgment on these claims should be denied.

## III. DESIGN DEFECT

Defendant is correct that California has eliminated strict liability for design defect claims in medical devices. *Garrett v. Howmedica Osteonics Corp.*, 214 Cal. App. 4th 173, 183-85 (Cal. App. 2013). However, in so doing, courts have made it clear that design defect claims continue to survive for failure to warn even in strict liability. *See Garrett*, 214 Cal. App. 4th at 183 ("Drug…manufacturers [and device makers], however, are not exempt from liability for manufacturing defects, failure to warn, and negligence."); *see also Carlin v. Superior Court*, 13 Cal. 4th 1104, 1117 (1996). The required warning must be sufficient to provide notice of any defect that a manufacturer knew or should have known existed. *See Garrett*, 214 Cal. App. 4th at 182 ("Under the negligence standard as reflected in comment k to section 402A of the Restatement Second of Torts… a manufacturer is liable for a design defect only if it failed to warn of a defect that it either knew or should have known existed.").

As previously described above regarding the failure to provide adequate warnings as to the Prolene mesh, Defendants knew or should have known about the defects. Thus, Plaintiff raises question of fact regarding the design defects of the Prolene Soft. Their design defect claims based on Defendants' failure to provide adequate warnings are not precluded under California law, and Defendants' motion for summary judgment should be denied on this ground.

## IV. MANUFACTURING DEFECT

In light of the Court's consistent rulings across these pelvic mesh MDLs as to manufacturing defect, Plaintiff does not intend to pursue a separate claim for "manufacturing defect," as such claim has been construed by the Court (not manufactured in accordance with design, or departure from manufacturer's design specifications). *See e.g. Tyree v. Boston Scientific Corp*., Case 2:12-cv-08633, Dkt. No. 446, pp.5-6 ("The plaintiff points to no evidence that the Obtryx sling departed from its intended design at the time it left BSC's control. Accordingly, BSC's Motion for Summary Judgment on the plaintiff's strict liability for manufacturing defect claim is GRANTED, and this claim is DISMISSED."). However, Plaintiff does intend to present evidence that Ethicon's manufacturing process and the raw materials used in the manufacture of its TVT products resulted in defects in the product, and in support of Plaintiff's negligence, design defect, and failure to warn claims, which is consistent with the Court's prior rulings. By not contesting Ethicon's motion as to "manufacture defect," Plaintiff does not forego, waive or in any way agree that evidence relating to Ethicon's manufacturing process and raw materials are restricted in any way.

## V. NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS AND GROSS NEGLIGENCE

Defendants' motion simply recites what they claim to be the applicable burden of proof and then state that Negligent Infliction of Emotional Distress and Gross Negligence should be dismissed for lack of evidence of "extreme and outrageous conduct." (Def. Mt. at 8). Defendants attempt to purport a heightened burden of proof for these two standards that do not exist.

In *Muse v. Brands, LLC v. Gentil*, 2015 WL 4572975, at *12, the intentional infliction of emotional distress cause of action was dismissed because the court could not plausibly infer that the defendant owed plaintiffs an independent tort duty. *Muse Brands, LLC v. Gentil*, No. 15-cv-01744-JSC, 2015 U.S. Dis. LEXIS 99143, at *32-33, 36-37 (N.D. Cal. July 28, 2015). Simply,

[t]he negligent causing of emotional distress is not an independent tort but the tort of negligence. The traditional elements of duty, breach of duty, causation, and damages apply. *Marlene F. v. Affiliated Psychiatric Med. Clinic, Inc.*, 48 Cal. 3d 583, 585, 257 Cal. Rptr. 98, 98, 770 P.2d 278, 278 (1989).

In addition, even if Negligent Infliction of Emotional Distress and Gross Negligence did require extreme and outrageous conduct, Plaintiff previously demonstrated such conduct in Defendants failure to inform physicians and patients of risks and complications that Ethicon knew to be associated with the Prolene Soft mesh devices.

As a result, Defendants' motion for summary judgment as to these counts should be denied, as no heightened burden of proof applies.[5]

## VI. FRAUD AND FRAUDULENT CONCEALMENT

Plaintiff has demonstrated the elements of her fraud claims. Plaintiff demonstrated previously that the Defendants' warnings were inadequate. Plaintiff also demonstrated that: 1) Defendants did conceal, false represent, and did not disclose the true risks of the Prolene Soft mesh; 2) Defendants did so knowingly; 3) intended to induce reliance of patients such as Ms. Garcia-Valdez (through her physician); 4) Mr. Garcia-Valdez relied on these representations (made to her physician) in obtaining adequate and accurate informed consent related to the Prolene Soft mesh; and 5) that Ms. Garcia-Valdez suffered injuries as a result.[6] Defendants motion for summary judgment on this claim should be denied.

## VII. CONSUMER PROTECTION LAW CLAIMS

[5] Defendants based their arguments solely on the purported need to meet a higher standard and not an absence of evidence to support the cause of action generally, Plaintiff therefore did not further detail that supporting evidence.
[6] *City of Santa Clara v. Atl. Richfield Co.*, 137 Cal. App. 4th 292, 345 (2006).

Plaintiff does not intend to pursue a claim for consumer protection laws in this case, so this argument is moot.

## VIII. CONSTRUCTIVE FRAUD

Plaintiff does not intend to pursue a claim for constructive fraud in this case, so this argument is moot.

## IX. UNJUST ENRICHMENT

Plaintiff does not intend to pursue claims for unjust enrichment in this case, so this argument is moot.

## X. BREACH OF WARRANTY

Plaintiff does not intend to pursue claims for breach of warranty in this case, so this argument is moot.

## CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that the Court enter an Order denying Defendants' Motion for Partial Summary Judgment.

Date: October 25, 2018

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on this date I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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